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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,333	07/26/2001	Franco Pamparana	101615-00012	5701

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EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,333	PAMPARANA, FRANCO	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14,16,18-20,22,24,25,27,28 and 30-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14,16,18-20,22,24,25,27,28 and 30-35* is/are rejected.

7)☒ Claim(s) *31,32,34 and 35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 12-14, 16, 18-20, 22, 24, 25, 27, 28 AND 30-35 ARE PRESENTED FOR EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 11, 2005 has been entered.

Accordingly, claims 12, 18, 24 and 27 have been amended. Also, the Information Disclosure Statement has been entered. As reflected by the attached, completed copy of form PTO-1449, the Examiner has considered the references cited thereon.

Claim Objection

Claims 31, 32, 34 and 35 are objected to because of the following informalities:

The claims recited "from about 25%" as a lower limit, which includes a % of not only above 25% , but also approximately 25%. A lower limit of approximately 25% is not supported in the claims from which these claims depend where a lower limit of "greater than 25%" is recited. Appropriate correction, i.e., deletion of the term "about" is required.

Claim Rejection - 35 USC § 103

Claims 12-14, 16, 18-20, 22, 24, 27, 28 and 30-35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Breivik et al. (U.S. Patent No. 5,502,077) in view of

Harrison's Principles of Internal Medicine ("Harrison's), each of record, for the reasons of record as set forth in the previous Office action dated May 23, 2005.

Applicant's arguments at pages 6-9 of the above referenced submission have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

In particular, because Applicant's conclusion of the impropriety of the present rejection rests upon a faulty premise, i.e., that Breivik et al. "*is limited to* the prevention of hypertension, hypertriglyceridemia, and high coagulation factor VII phospholipids complex *in otherwise healthy patients* having undetected moderate hypertension without previous illness" (emphasis added), (Applicant's above referenced submission at page 9, first full paragraph), Applicant's arguments which support such a conclusion are equally as faulty and do not lead the Examiner to a conclusion of non-obviousness of the presently claimed subject matter.

The Examiner is guided in his opinion that Applicant's premise that Breivik et al. "*is limited to* the prevention of hypertension, hypertriglyceridemia, and high coagulation factor VII phospholipids complex *in otherwise healthy patients* having undetected moderate hypertension without previous illness" is, in fact, faulty by the Court's decision in In re Courtright, 153 USPQ 735 (CCPA 1967), "One cannot ignore broader, instructive disclosure of reference at expense of reliance only on specific examples, where broader disclosure teaches how to modify exemplary compositions to produce certain desired results.". Here, Breivik et al. has limited their patient population to otherwise healthy patients having undetected moderate hypertension without previous illness only in studies reported by the patentees at cols. 6-10. One cannot, however, simply ignore the fact that Breivik et al. also generally discloses that the composition disclosed

therein may be used in a patient population that is not as limited. The broadest enabled concept provided by Breivik et al. is to use the eicosapentaenoic/docosahexaenoic composition "for the treatment or prophylaxis of multiple risk factors for cardiovascular diseases." (see Breivik et al. at the last line of the abstract and col. 2, lines 54-57).

It remains the Examiner's position that based on the teachings of Breivik et al. and Harrison's, the selection of any specific patient population in whom to practice the invention of Breivik et al., such as patients who have suffered myocardial infarction, would have been a matter well within the purview of the skilled artisan. This position is stated and expanded upon in the previous Office actions, e.g., see the Office action dated May 23, 2005 at page 2-5.

Respecting the Harrison's reference, Applicant has dismissed the teachings therein by stating that "nothing in the cited reference describes the administration of omega-3 fatty acids for any indication related to myocardial infarction" (Applicant's submission at page 7, end of the second full paragraph). Harrison's, however, was not relied upon for this purpose. For the purposes that the Examiner *did* rely on Harrison's, i.e., to show that myocardial infarction patients was a population known to the skilled artisan and that myocardial infarction was known to be associated with the risk factors identified and treated by Breivik et al., Harrison's remains properly relied on and clearly supports the Examiner's conclusion of obviousness, (see, for example, the Office action dated May 23, 2005 at page 5).

At page 8 of Applicant's submission, Applicant has urged that the Examiner has further erred in his conclusion of obviousness by relying on teachings which relate to the development of myocardial infarction in the general population rather than the secondary prevention of adverse cardiovascular events in a patient who has survived a myocardial infarction. Buttressing

their position, Applicant has urged that one skilled in the art would understand that patients having suffered a myocardial infarction have increased cardiovascular risk factors related to the reoccurrence of adverse cardiovascular events. In support of this position, Applicant has relied on The American College of Cardiology and the American Heart Association Practice guidelines, ("ACC/AHA guidelines") which were developed specifically for the treatment of myocardial infarction. The Examiner recognizes that these guidelines do not involve the administration of omega-3 fatty acids as presently claimed, (see Applicant's submission at page 8, first full paragraph).

The guidelines provided in the ACC/AHA guidelines involve administration of oxygen, nitroglycerine and, *inter alia*, aspirin (see pages 1342+ of reference "3" in the most recent IDS supplied by Applicant). In response to the position, it is noted that nothing in these guideline preclude the additional administration of omega-3 fatty acids as is presently claimed. Further, the present claims recite "comprising administering to said patient", i.e., claims 12, 18, 24 and 27, which, because of the transition term "comprising", fails to preclude the administration of additional compounds other than those explicitly recited, (see MPEP § 2111.03). Also, the protocols advanced in these guidelines are just that, guidelines. Such do not preclude one of ordinary skill in the art from utilizing other treatment protocols such as the protocol suggested by the art relied on by the Examiner.

Finally, at the paragraph bridging pages 8-9 of their submission, Applicant has urged that Harrison's actually teaches away from the Examiner's conclusion. The Examiner does not agree and believes that Harrison's supports the Examiner's position (see, for example, the Office action dated May 23, 2005 at pages 4-5). Applicant points to a teaching in Harrison's at page

1076 that "discusses 'postinfarction risk stratification and management stating that 'many clinical factors have been identified with an increase in cardiovascular risk following initial recovery from a myocardial infarction.' As such, 'therapy must be individualized depending on the relative importance of the risk(s) present and the degree of benefit to be achieved by specific therapy including revascularization or the use of pharmacologic agents.'.

The Examiner believes this to buttress his position because Breivik et al. explicitly teaches that "where EPA and DHA are present in relative amounts of 1:2 to 2:1, and constitute at least 75% of the total fatty acids, (compare to, for example, Applicant's claim 12 "the content of EPA+DHA in the mixture is greater than 25% by weight"), has *a surprisingly advantageous effect* on all the above mentioned risk factors for cardiovascular diseases." (col. 2, lines 53-57). It has been clearly established throughout the record that myocardial infarction is a cardiovascular disease and thus would have been included in Breivik et als. "cardiovascular diseases" and it has also been cogently argued by the Examiner that a patient who had suffered such a disease would have been reasonably recognized by one of ordinary skill in the art as being a patient encompassed by Breivik et al. Therefore, contrary to Applicant's contention, Harrison's is not seen to teach away from the Examiner's conclusion of obviousness.

For the above reasons, as well as the fact that Applicant has failed to present ***any*** objective evidence that the presently claimed method provides for any result that would not have been expected by one of ordinary skill in the art, the Examiner is compelled to maintain that the rejection of claims 12-14, 16, 18-20, 22, 24, 27, 28 and 30-35 under 35 U.S.C. 103(a) as being unpatentable over Breivik et al. (U.S. Patent No. 5,502,077) in view of Harrison's Principles of

Internal Medicine ("Harrison's), each of record, for the reasons of record as set forth in the previous Office action dated May 23, 2005 is proper.

None of the claims are allowed

The present action is not being made final so that Applicant may be afforded the opportunity to consider what further action will be taken.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

October 13, 2005